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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/829,126

04/21/2004

Henry DiGregorio

NOR / 1176

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37172

7590

01/22/2009

WOOD, HERRON & EVANS, LLP (NORDSON)

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

NOTIFICATION DATE

DELIVERY MODE

01/22/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/829,126	<b>Applicant(s)</b> DIGREGORIO ET AL.	
	<b>Examiner</b> THEODORE J. STIGELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 18-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/16/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Claim Objections***

The claim objections have been withdrawn in light of the amendments filed on 10/22/2008.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4, 6, 8, 18-20, 22-25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (2,591,046). Brown discloses a syringe that is capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed (functional language) comprising a barrel (11) including a first opening (proximal end), a second opening (distal end), a sidewall including an inwardly-facing surface, a plurality of axially-extending grooves (25, 35) defined in the surface, and a tapered region (not numbered, tapered end of the barrel) between the surface and the second opening, the surface and the grooves configured to be contacted by the fluid, and the axially extending grooves extending from approximately the first opening

to approximately the tapered region. In regards to claims 18-21, the grooves (25, 35) inherently will have a textured surface which can be considered the claimed surface feature. Brown further discloses pistons (16, 26) that could be located before the grooves if the syringe were frozen.

Claims 1, 3-4, 6, 8, 18-20, and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bachynsky (5,971,953). Bachynsky discloses a syringe that is capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed (functional language) comprising a barrel (11) including a first opening (proximal end), a second opening (distal end), a sidewall including an inwardly-facing surface, a plurality of axially-extending grooves (30) defined in the surface, and a tapered region (17) between the surface and the second opening, the surface and the grooves configured to be contacted by the fluid, and the axially extending grooves extending from approximately the first opening to approximately the tapered region. In regards to claims 18-21, the surface feature is ribs (29) and recesses (31). Regarding claim 26, recess (31) increases the surface area. Bachynsky further discloses pistons (32, 33) that could be located before the grooves if the syringe were frozen.

Claims 1, 3-4, 6-8, 18-20, 22-25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Reinhard et al. (5,788,670). Reinhard discloses a syringe that is capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed (functional language) comprising a barrel (2) including a first opening (proximal end), a second opening (distal end), a sidewall including an

inwardly-facing surface, a plurality of axially-extending grooves (5) defined in the surface, and a tapered region (4) between the surface and the second opening, the surface and the grooves configured to be contacted by the fluid, and the axially extending grooves extending from approximately the first opening to approximately the tapered region. In regards to claims 18-21, the grooves (5) inherently will have a textured surface which can be considered the claimed surface feature. Reinhard further discloses piston (11) that could be located before the grooves if the syringe were frozen.

Claims 1, 3, 6-8, 18-20, and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Nisho Co. Ltd. (JP 8-57,051). Nisho discloses a syringe that is capable of dispensing a fluid susceptible to freeze-thaw voids wherein the inner surface of the syringe is roughened (which will inherently produce grooves) to have an average surface roughness of about 0.92 micrometers.

Claims 1, 3-8 and 18-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Wyatt (US 2005/0221035). Wyatt discloses a syringe (see at least paragraph 0015) designed to reduce freeze thaw voids wherein the inner surface of the syringe is roughened (which will inherently produce grooves) to have an average surface roughness of between about 2.9 micrometers (see at least paragraph 0017).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nisho Co. Ltd. (JP 8-57,051). Nisho discloses a syringe including most of the limitations but fails to include an average surface roughness of between 2.5-5.1 microns. The applicant has failed to show that the recited range works better than the disclosed roughness of Nisho which is about 0.92 microns. Therefore, these limitations are being treated as design considerations which fail to patentably distinguish over the prior art.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, Bachynsky, Reinhard, Wyatt, or Nissho in view of Carrell et al (USPN 4,846,796). Brown, Bachynsky, Reinhard, Wyatt, or Nissho each individually meet the claim limitations as described above but each one fails to include a pressure sleeve.

However, Carrell discloses such a sleeve for increasing the safety of the device to the patient. At the time of the invention, it would have been obvious to incorporate the sleeve of Carrell into the invention of Brown, Bachynsky, Reinhard, Wyatt, or

Nissho. The motivation for the incorporation would have been done in order to increase the safety of the device to the patient as taught by Carrell.

### ***Response to Arguments***

Applicant's arguments filed 10/22/2008 have been fully considered but they are not persuasive.

*Brown (2,591,046), Bachynsky (5,971,953), Reinhard et al. (5,788,670)*

In response to the applicant's argument that the references do not disclose axial grooves extending from proximate the first opening to proximate the tapered region, the examiner respectfully disagrees. The examiner maintains that "proximate" is a broad term and that the grooves of the references extend from proximate the first opening to proximate the tapered region. The examiner also maintains that the syringes of the references are capable of dispensing a fluid susceptible to void formation.

*Nisho Co. Ltd. (JP 8-57,051) and Wyatt (US 2005/0221035)*

In response to the applicant's argument that Nisho and Wyatt do not disclose a plurality of axial grooves defined in the inwardly-facing surface, the examiner respectfully disagrees. The examiner maintains that Nisho and Wyatt disclose roughening the inside surface of a syringe which will inherently produce microscopic grooves. The grooves will at least extend partially in an axial direction and can therefore be considered axial grooves.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763